

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

BAYER SCHERING PHARMA AG, BAYER )  
HEALTHCARE PHARMACEUTICALS )  
INC., and SCHERING CORPORATION, )

Plaintiffs, )

v. )

LUPIN LTD. and LUPIN )  
PHARMACEUTICALS, INC., )

Defendants. )

Civil Action No. 1:10-cv-00127-SLR

**ANSWER, DEFENSES, COUNTERCLAIM AND JURY DEMAND OF  
DEFENDANTS LUPIN LTD. AND LUPIN PHARMACEUTICALS, INC.**

Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (“LPI”) (collectively, “Lupin”) hereby answer the Complaint of Plaintiffs Bayer Schering Pharma AG, Bayer HealthCare Pharmaceuticals Inc., and Schering Corporation (collectively, “Plaintiffs”)—for which every allegation not expressly admitted is denied—as follows:

**NATURE OF THE ACTION**

1. Paragraph 1 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Lupin admits that this is an action for alleged patent infringement. Lupin further admits that Lupin Ltd. has filed an abbreviated new drug application (“ANDA”) seeking United States Food and Drug Administration (“FDA”) approval for ciprofloxacin oral suspension, 250 mg/5mL and 500 mg/5mL, prior to the expiration of U.S. Patent No. 5,695,784 (“784 patent”). Lupin denies all remaining allegations in Paragraph 1.

**PARTIES**

2. Lupin is without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 2, and therefore denies all such allegations.

3. Lupin is without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 3, and therefore denies all such allegations.

4. Lupin is without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 4, and therefore denies all such allegations.

5. Lupin admits that Lupin Ltd. is an Indian corporation located solely in India, that Lupin Ltd. has a place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (W), Mumbai 400 051, India, and that Lupin Ltd. develops and manufactures quality pharmaceuticals. Lupin denies all remaining allegations in Paragraph 5.

6. Paragraph 6 contains legal conclusions to which no answer is required. To the extent that an answer is required, Lupin admits that LPI is a Virginia corporation having a place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland, 21202. Lupin further admits that LPI is a wholly-owned subsidiary of Lupin Ltd. Lupin denies all remaining allegations in Paragraph 6.

7. Denied.

8. Denied.

**JURISDICTION AND VENUE**

9. Paragraph 9 contains legal conclusions to which no answer is required. To the extent that an answer is required, Lupin admits that subject matter jurisdiction is proper for the claims directed against Lupin Ltd. only. Lupin denies all remaining allegations in Paragraph 9.

10. Paragraph 10 contains legal conclusions to which no answer is required. To the extent that an answer is required, Lupin denies all the allegations of Paragraph 10. Answering further, to conserve the resources of the parties and the Court, Lupin Ltd. does not contest personal jurisdiction for purposes of this action only.

11. Paragraph 11 contains legal conclusions to which no answer is required. To the extent that an answer is required, Lupin denies all the allegations of Paragraph 11. Answering further, to conserve the resources of the parties and the Court, LPI does not contest personal jurisdiction for purposes of this action only.

12. Paragraph 12 contains legal conclusions to which no answer is required. To the extent that an answer is required, Lupin denies all the allegations of Paragraph 12. Answering further, to conserve the resources of the parties and the Court, Lupin does not contest personal jurisdiction for purposes of this action only.

13. Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin denies all the allegations of Paragraph 13. Answering further, to conserve the resources of the parties and the Court, Lupin does not contest venue in this district for purposes of this action only.

#### **BACKGROUND**

14. Lupin admits that the electronic version of FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), identifies Cipro® (Ciprofloxacin) Oral Suspension 250 mg/5 mL and 500 mg/5 mL as approved under New Drug Application ("NDA") No. 20-780, and that the FDA-approved labeling for Cipro® (Ciprofloxacin) Oral Suspension 250 mg/5 mL and 500 mg/5 sets forth any approved indications or uses for those products. Lupin denies all remaining allegations in Paragraph 14.

15. Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the United States Patent and Trademark Office (“PTO”), the PTO issued U.S. Patent No. 5,695,784 (“’784 patent”), titled “FLAVOR-MASKED PHARMACEUTICAL COMPOSITIONS,” on or about December 9, 1997, to Norbert Pöllinger, Johannes Michaelis, Klaus Benke, Roland Rupp, and Manfred Bücheler; that the cover page of the ‘784 patent identifies “Bayer Aktiengesellschaft” as the purported “assignee”; and that what purports to be a copy of the ‘784 patent is attached to the Complaint as Exhibit A. Lupin denies that the ‘784 patent was “duly and legally issued,” and further denies all remaining allegations of Paragraph 15.

16. Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Lupin is without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 16, and therefore denies all such allegations.

17. Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Lupin admits that the electronic version of the Orange Book identifies “BAYER HLTHCARE” as the “applicant” for NDA No. 20-780 for CIPRO<sup>®</sup>, and that the ‘784 patent is listed in the Orange Book in connection with CIPRO<sup>®</sup>. Lupin denies all remaining allegations of Paragraph 17.

18. Lupin is without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 18, and therefore denies all such allegations.

19. Lupin admits that Lupin Ltd. sent the required notice to Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc., among others, notifying the recipients

that Lupin Ltd. had filed an ANDA with FDA for ciprofloxacin oral suspension, 250 mg/5mL and 500 mg/5mL; and that Lupin Ltd.'s ANDA contains a "paragraph IV certification" stating that, in Lupin Ltd.'s opinion and to the best of its knowledge, the '784 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in Lupin Ltd.'s ANDA. Lupin further admits that Lupin Ltd.'s notice letter satisfies all statutory and regulatory requirements. Lupin denies that LPI has submitted an ANDA for ciprofloxacin oral suspension, 250 mg/5mL and 500 mg/5mL, and further denies that LPI sent any notice letter. Lupin denies all remaining allegations of Paragraph 19.

20. Lupin admits that Lupin Ltd. sent the required notice to Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc., among others, notifying the recipients that Lupin Ltd. had filed an ANDA with FDA for ciprofloxacin oral suspension, 250 mg/5mL and 500 mg/5mL; and that Lupin Ltd.'s ANDA contains a "paragraph IV certification" stating that, in Lupin Ltd.'s opinion and to the best of its knowledge, the '784 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in Lupin Ltd.'s ANDA. Lupin further admits that Lupin Ltd.'s notice letter satisfies all statutory and regulatory requirements. Lupin denies that LPI has submitted an ANDA for ciprofloxacin oral suspension, 250 mg/5mL and 500 mg/5mL, and further denies that LPI sent any notice letter. Lupin denies all remaining allegations of Paragraph 20.

21. Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Lupin denies all allegations of Paragraph 21.

22. Lupin admits that Lupin Ltd. sent the required notice to Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc., among others, notifying the recipients

that Lupin Ltd. had filed an ANDA with FDA for ciprofloxacin oral suspension, 250 mg/5mL and 500 mg/5mL. Lupin denies all remaining allegations of Paragraph 22.

23. Paragraph 23 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Ltd.'s ANDA contains a "paragraph IV certification" stating that, in Lupin Ltd.'s opinion and to the best of its knowledge, the '784 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in Lupin Ltd.'s ANDA. Lupin denies all remaining allegations of Paragraph 23.

**AS TO THE ALLEGATIONS OF COUNT I**

24. Lupin repeats, reasserts and incorporates by reference its answers to the preceding paragraphs as if fully set forth herein.

25. Denied.

26. Denied.

27. Denied.

**AS TO THE ALLEGATIONS OF COUNT II**

28. Lupin repeats, reasserts and incorporates by reference its answers to the preceding paragraphs as if fully set forth herein.

29. Denied.

30. Denied.

31. Denied.

32. Denied.

33. Denied.

34. Denied.

35. Denied.

36. Paragraph 36 contains legal conclusions to which no answer is required. To the extent that an answer is required, Lupin admits that subject matter jurisdiction is proper for the claims directed against Lupin Ltd. under 35 U.S.C. § 271(e)(2)(A) only. Lupin denies all remaining allegations in Paragraph 36.

37. Denied.

38. Denied.

39. Denied.

**AS TO THE ALLEGATIONS OF COUNT III**

40. Lupin repeats, reasserts and incorporates by reference its answers to the preceding paragraphs as if fully set forth herein.

41. Denied.

42. Denied.

43. Denied.

**AS TO THE ALLEGATIONS OF COUNT IV**

44. Lupin repeats, reasserts and incorporates by reference its answers to the preceding paragraphs as if fully set forth herein.

45. Denied.

46. Denied.

47. Denied.

48. Denied.

49. Denied.

50. Denied.

51. Denied.

52. Paragraph 52 contains legal conclusions to which no answer is required. To the extent that an answer is required, Lupin admits that subject matter jurisdiction is proper for the claims directed against Lupin Ltd. under 35 U.S.C. § 271(e)(2)(A) only. Lupin denies all remaining allegations in Paragraph 52.

53. Denied.

54. Denied.

55. Denied.

\* \* \*

Lupin denies all allegations not expressly admitted herein. Lupin further denies that Plaintiffs are entitled to any of the relief requested, and requests that Plaintiffs' Complaint be dismissed with prejudice and that Lupin be awarded its fees and costs incurred defending this suit under 35 U.S.C. § 285.

### **DEFENSES**

Without prejudice to the denials set forth in its Answer, without admitting allegations of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiffs, Lupin asserts the following defenses to the Complaint:

#### **First Defense**

The manufacture, use, sale, offer for sale, or importation of the ciprofloxacin oral suspension, 250 mg/5mL and 500 mg/5mL, that is the subject of Lupin Ltd.'s ANDA has not infringed, does not infringe, and will not, if marketed, infringe, either directly or indirectly, any valid and/or enforceable claim of U.S. Patent No. 5,695,784 ("784 patent"), either literally or under the doctrine of equivalents.

#### **Second Defense**

The '784 patent is invalid under one or more provisions of 35 U.S.C. § 101 *et seq.*

**Third Defense**

The Court lacks subject matter jurisdiction over any and all claims directed toward Lupin Pharmaceuticals, Inc. ("LPI").

**Fourth Defense**

LPI is not a proper party to this suit.

**Fifth Defense**

The Court lacks subject matter jurisdiction over any and all claims arising pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

**Sixth Defense**

The Complaint fails to state a claim upon which relief can be granted.

**Seventh Defense**

The Complaint fails to state a claim for willful infringement.

**Eighth Defense**

Any additional defenses or counterclaims that discovery may reveal, including, but not limited to, defenses of unenforceability.

**COUNTERCLAIMS**

Lupin Ltd., for its Counterclaim against Plaintiffs Bayer Schering Pharma AG, Bayer HealthCare Pharmaceuticals Inc., and Schering Corporation (collectively, "Plaintiffs/Counterclaim-Defendants"), alleges as follows:

**The Parties**

1. Lupin Ltd. is a corporation organized and existing under the laws of India, having a place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (W), Mumbai 400 051, India.

2. Bayer Schering Pharma AG (“Bayer Schering”) purports to be a corporation organized and existing under the laws of the Federal Republic of Germany, with its principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.

3. Bayer HealthCare Pharmaceuticals Inc. (“Bayer HealthCare”) purports to be a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

4. Schering Corporation (“Schering”) purports to be a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

#### **Jurisdiction and Venue**

5. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (“MMA”) (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

6. This Court has original jurisdiction over the subject matter of this Counterclaim under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

7. This Court has personal jurisdiction over, and venue for this Counterclaim is proper in this District because, Plaintiffs/Counterclaim-Defendants have purposefully availed

themselves of the rights and privileges of this forum by suing Lupin Ltd. in this District, and because Plaintiffs/Counterclaim-Defendants conduct substantial business in, and have regular and systematic contacts with, this District.

**Patents-In-Suit**

8. On or about December 9, 1997, the United States Patent and Trademark Office (“PTO”) issued U.S. Patent No. 5,695,784 (“the ‘784 patent”), entitled “Flavor-Masked Pharmaceutical Compositions,” to Norbert Pöllinger, Johannes Michaelis, Klaus Benke, Roland Rupp, and Manfred Bücheler. A true and correct copy of the ‘784 patent is attached hereto as Exhibit A.

9. On or about October 24, 2000, The PTO issued U.S. Patent No. 6,136,347 (“the ‘347 patent”), entitled “Flavor-Masked Pharmaceutical Compositions,” to Norbert Pöllinger, Johannes Michaelis, Klaus Benke, Roland Rupp, and Manfred Bücheler. A true and correct copy of the ‘347 patent is attached hereto as Exhibit B.

10. Plaintiffs/Counterclaim-Defendants purport and claim to own and/or have the rights to enforce the ‘784 and ‘347 patents.

11. Bayer HealthCare has submitted information on the ‘784 patent and the ‘347 patent to FDA for listing in the Orange Book in connection with Cipro®, thus alleging and asserting that such patents “claim[] the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.”

12. On or about February 17, 2010, Plaintiffs/Counterclaim-Defendants sued Lupin Ltd. in this District alleging infringement of the ‘784 patent.

**COUNT I**

**(Declaration of Non-Infringement of the '784 Patent)**

13. Lupin Ltd. realleges and incorporates by reference the allegations of Paragraphs 1-12.

14. A present, genuine, and justiciable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin Ltd. regarding, *inter alia*, the non-infringement of the '784 patent.

15. The manufacture, use, sale, offer for sale or importation of the ciprofloxacin oral suspension, 250 mg/5mL and 500 mg/5mL, that is the subject of Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe, either directly or indirectly, any valid and/or enforceable claim of the '784 patent.

16. Lupin Ltd. is entitled to a declaration that the manufacture, use, sale, offer for sale or importation of the ciprofloxacin oral suspension, 250 mg/5mL and 500 mg/5mL, that is the subject of Lupin Ltd.'s ANDA, has not infringed, does not infringe, and would not, if marketed, infringe, either directly or indirectly, any valid and/or enforceable claim of the '784 patent.

**COUNT II**

**(Declaration of Invalidity of the '784 Patent)**

17. Lupin Ltd. realleges and incorporates by reference the allegations of Paragraphs 1-16.

18. A present, genuine, and justiciable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin Ltd. regarding, *inter alia*, the invalidity of the '784 patent.

19. The '784 patent is invalid under one or more provisions of 35 U.S.C. § 101 *et seq.*

20. Lupin Ltd. is entitled to a declaration that '784 patent is invalid.

**COUNT III**  
**(Declaration of Non-Infringement of the '347 Patent)**

21. Lupin Ltd. realleges and incorporates by reference the allegations of Paragraphs 1-20.

22. A present, genuine, and justiciable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin Ltd. regarding, *inter alia*, the non-infringement of the '347 patent.

23. The manufacture, use, sale, offer for sale or importation of the ciprofloxacin oral suspension, 250 mg/5mL and 500 mg/5mL, that is the subject of Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe, either directly or indirectly, any valid and/or enforceable claim of the '347 patent.

24. Lupin Ltd. is entitled to a declaration that the manufacture, use, sale, offer for sale or importation of the ciprofloxacin oral suspension, 250 mg/5mL and 500 mg/5mL, that is the subject of Lupin Ltd.'s ANDA, has not infringed, does not infringe, and would not, if marketed, infringe, either directly or indirectly, any valid and/or enforceable claim of the '347 patent.

**COUNT IV**  
**(Declaration of Invalidity of the '347 Patent)**

25. Lupin Ltd. realleges and incorporates by reference the allegations of Paragraphs 1-24.

26. A present, genuine, and justiciable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin Ltd. regarding, *inter alia*, the invalidity of the '347 patent.

27. The '347 patent is invalid under one or more provisions of 35 U.S.C. § 101 *et seq.*

28. Lupin Ltd. is entitled to a declaration that '347 patent is invalid.

**REQUEST FOR RELIEF**

WHEREFORE, Defendant/Counterclaim-Plaintiff Lupin Ltd. respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiffs/Counterclaim-Defendants Bayer Schering Pharma AG, Bayer HealthCare Pharmaceuticals Inc., and Schering Corporation as follows:

- (a) Declaring that the manufacture, use, sale, offer for sale or importation of the ciprofloxacin oral suspension, 250 mg/5mL and 500 mg/5mL, that is the subject of Lupin Ltd.'s ANDA, has not infringed, does not infringe, and will not, if marketed, infringe, either directly or indirectly, any valid and/or enforceable claim of the '784 patent;
- (b) Declaring that the '784 patent is invalid;
- (c) Declaring that the manufacture, use, sale, offer for sale or importation of the ciprofloxacin oral suspension, 250 mg/5mL and 500 mg/5mL, that is the subject of Lupin Ltd.'s ANDA, has not infringed, does not infringe, and will not, if marketed, infringe, either directly or indirectly, any valid and/or enforceable claim of the '347 patent;
- (d) Declaring that the '347 patent is invalid;
- (e) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Lupin Ltd. its attorney fees, costs, and expenses in this action;
- (f) Awarding Lupin Ltd. its costs; and
- (g) Awarding Lupin Ltd. any further and additional relief as the Court deems just and proper.

**Jury Demand**

Lupin Ltd. and LPI hereby demand a trial by jury as to all issues so triable.

Respectfully submitted,

**PHILLIPS, GOLDMAN & SPENCE, P.A.**

Dated: April 14, 2010

By: \_\_\_\_\_

  
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